

AMENDMENTS TO THE CLAIMS

Listing of Claims:

This listing of claims will replace all prior versions and listings of the claims in the application:

Claims 1-20 (Cancelled).

21. (Currently Amended) A directly compressible tablet ~~adapted to disintegrate~~ disintegrating in the mouth on contact with saliva in less than 30 seconds, forming an easy-to-swallow suspension and having a friability of less than 1%, said tablet comprising:

a lubricating agent in powder form, and

a dry mixture of an active substance and excipients including a disintegrating agent and a soluble agent with binding properties, and

~~a lubricating agent in powder form,~~

wherein more than half of the lubricating agent is distributed on the tablet outer surface and the rest of the lubricating agent, if any, is comprised in the dry mixture, and wherein the active substance is in a form of ~~coated~~ microcrystals or ~~coated~~ microgranules that are uniformly coated with a polymer coating.

22. (Previously Presented) Tablet in accordance with Claim 21, wherein a largest dimension of the tablet is greater than 5 mm.

23. (Previously Presented) Tablet in accordance with Claim 21, wherein the lubricating agent is a pharmaceutically acceptable lubricating agent having a melting point of at least 35°C.

24. (Previously Presented) Tablet in accordance with Claim 21, wherein the lubricating agent is a member selected from the group consisting of magnesium stearate, sodium stearyl fumarate, stearic acid and micronized polyoxyethylene glycol.

25. (Previously Presented) Tablet in accordance with Claim 21, wherein the lubricating agent is magnesium stearate.

26. (Previously Presented) Tablet in accordance with Claim 21, wherein a quantity of lubricating agent is in a range of 0.2 to 10 parts per 1000 based on a weight of lubricating agent per total weight of the tablet.

27. (Previously Presented) Tablet in accordance with Claim 21, wherein the lubricating agent has a particle size distribution less than 30 microns, such that constituent particles of the lubricating agent adhere to a surface when the lubricating agent is sprayed against the surface.

28. (Previously Presented) Tablet in accordance with Claim 21, wherein the disintegrating agent is a member selected from the group consisting of cross-linked sodium carboxymethylcellulose, croscopovidone and their mixtures.

29. (Previously Presented) Tablet in accordance with Claim 21, wherein the excipients include a permeabilising agent, a solubilising agent, sweeteners, flavors, and colorings.

30. (Currently Amended) Tablet in accordance with Claim 21, wherein the tablet is ~~adapted to withstand being~~ packaged in and delivered from blisters composed entirely of aluminium, said blisters optionally including a cover of a plastic material which is to be torn off before opening.

31. (Currently Amended) Process for producing a tablet in accordance with Claim 21, wherein the process comprises:

- choosing, firstly, an active substance in a form of ~~coated~~ microcrystals or ~~coated~~ microgranules that are uniformly coated with a polymer coating, and secondly, a set of excipients including a disintegrating agent, a soluble agent with binding properties, and a lubricating agent in powder form;
- dry mixing the active substance and the excipients to form a mixture, provided that more than half of the lubricating agent is not included in the mixture;

- applying more than half of the lubricating agent onto walls surrounding a cavity of a compression device;

- feeding a quantity of the mixture necessary to form a tablet into the cavity of the compression device within which the mixture is to be compressed and onto the walls of which more than half of the lubricating agent has been applied in advance; and

- compressing the mixture using compression forces and ejecting the tablet formed.

32. (Previously Presented) Process in accordance with Claim 31, wherein compression forces are in a compression force range from 3kN to 50 kN.

33. (Previously Presented) Tablet according to Claim 21, wherein the friability of the tablet is less than 0.5%.

34. (Previously Presented) Tablet in accordance with Claim 22, wherein the largest dimension of the tablet is greater than 17 mm.

35. (Previously Presented) Tablet in accordance with Claim 23, wherein the lubricating agent has a melting point higher than 50°C.

36. (Previously Presented) Tablet in accordance with Claim 26, wherein the quantity of lubricating agent is in the range of 3 to 6 parts per 1000.

37. (Previously Presented) Tablet in accordance with Claim 27, wherein the lubricating agent has a particle size distribution less than 10 microns.

38. (Previously Presented) Process in accordance with Claim 32, wherein the compression force range is 4 kN to 40 kN.

39. (Previously Presented) Process in accordance with Claim 38, wherein the compression force range is 5 kN to 25 kN.

40. (Previously Presented) Process in accordance with Claim 31, wherein none of the lubricating agent is dry mixed with the active substance and other excipients to form a mixture,

and all of the lubricating agent is applied onto the walls surrounding the cavity of the compression device, such that all of the lubricating agent of the tablet is distributed on an outer surface of the tablet.

41. (Previously Presented) Tablet in accordance with Claim 21, wherein all of the lubricating agent of the tablet is distributed on an outer surface of the tablet.

42. (Previously Presented) Process in accordance with Claim 31, wherein the lubricating agent is a member selected from the group consisting of magnesium stearate, sodium stearyl fumarate, stearic acid and micronized polyoxyethylene glycol.

43. (Previously Presented) Process in accordance with Claim 31, wherein the disintegrating agent is a member selected from the group consisting of cross-linked sodium carboxymethylcellulose, crospovidone and their mixtures.

44. (Previously Presented) Process in accordance with Claim 31, wherein the excipients further include a permeabilising agent, a solubilising agent, sweeteners, flavors and colorings.

45. (Currently Amended) Process for reducing the friability of a directly compressible tablet comprising a step of spraying a lubricating agent on a surface of compression punches such that more than half of the lubricating agent is distributed on a tablet outer surface, said tablet comprising

a lubricating agent in powder form, and

a dry mixture of an active substance and excipients including at least a disintegrating agent, and a soluble agent with binding properties, ~~and a lubricating agent in powder form,~~ wherein the active substance is in a form of ~~coated~~ microcrystals or ~~coated~~ microgranules that are uniformly coated with a polymer coating.

46. (Previously Presented) Process in accordance with Claim 45, wherein the lubricating agent is a member selected from the group consisting of magnesium stearate, sodium stearyl fumarate, stearic acid and micronized polyoxyethylene glycol.

Application Serial No. 09/914,544
Response to Advisory Action dated March 3, 2009
Amendment After Entry of RCE dated March 13, 2009

47. (Previously Presented) Process in accordance with Claim 45, wherein the disintegrating agent is a member selected from the group consisting of cross-linked sodium carboxymethylcellulose, crospovidone and their mixtures.